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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,778	12/17/2001	Douglas D. Sjostrom	02-35-0385 / 00167-456001	4406
7590	05/19/2004		EXAMINER	
JOEL R. PETROW Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116			NGUYEN, VI X	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,778	SJOSTROM, DOUGLAS D.	
	Examiner	Art Unit	
	Victor X Nguyen	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 February 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 and 4-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Thimsen et al (U.S. 4,844,064).

Thimsen et al disclose in figs. 2-5, a surgical cutting instrument having the limitations of claims 1, 18 and 25, including: a cutting instrument (11); an outer member (14) has an opening (16, 17) bounded by a cutting edge (58); a helical knife (18) coupled to the outer member for rotation relative to the outer member. The helical knife (18) has an edge (74, 76) to slide into tissue and the edge extends through the opening to form an outer periphery of the cutting instrument (see col. 6, lines 57-68). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the surgical cutting instrument of Thimsen would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claims 2, 4, and 28-29, wherein an inner member (44) receives within the outer member. The helical knife (18) is located at a distal end of the inner member; and wherein the inner member defines an aspiration opening (see col. 6, lines 36-67).

Regarding claims 5-7 and 30-32, wherein the edge (74,76) of the helical knife (18) includes a helical channel (58, 70, fig. 3); wherein the helical channel has a pitch that increases from the distal end to the proximal end; and wherein the helical channel terminates in an opening through a wall of the inner member.

Regarding claims 8-11 and 33-35, wherein the device further includes a hub (12); wherein the outer member (14) defines a fluid. The cutting edge (58) is located at a distal end of the outer member. The outer member (14) tapers to the cutting edge.

Regarding claims 12-13 and 36-37, wherein the cutting edge includes a circumferential and a circular in shape (figs. 3-4).

Regarding claims 14-17 and 38-41, wherein the cutting edge is part circumferential, circular and oblong in shape; and wherein the outer member includes a shield portion (fig. 2).

Regarding claims 19-24, wherein the helical knife (18) is on an inner member (44) and the cutting portion is on an outer member (14); wherein transporting the cut tissue along a helical channel defines by the helical knife; wherein aspirating the cut tissue is through the inner member. The aspirating fluid is through an opening in the outer member (14).

Regarding claims 26-27, wherein the edge of helical knife (18) extends distally through the opening (16, 17); and wherein the cutting edge and the edge of helical knife (figs. 1 and 5) configure to cut tissue.

3. Claims 1, 18 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Banko (U.S. 4,167,944).

Banko discloses in figs. 1-3, a surgical cutting instrument having the limitations of claims 1, 18 and 25, including: a cutting instrument (10); an outer member (56) has an opening (60, 64) bounded by a cutting edge (37a); a helical knife (37b) coupled to the outer member for rotation relative to the outer member. The helical knife (37b) has an edge to slide into tissue and the edge extends through the opening to form an outer periphery of the cutting instrument (see col.3, lines 51-60). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the surgical cutting instrument of Banko would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.

See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thimsen et al (U.S. 4,844,064).

5. Thimsen et al are explained as before. Although, Thimsen et al do not disclose the inner member and the outer member is in the range of about 0.0005 to 0.002 inches. It would have been obvious matter of design choice to modify the inner member and the outer member is in the range of about 0.0005 to 0.002 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re-Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 2/23/2004 have been fully considered but they are not persuasive. Applicant's argues that the Thimsen fails to disclose a cutting instrument having an edge of a helical knife extending through an opening of an outer member to form an outer periphery of the cutting instrument. The examiner, respectfully, disagrees. As the examiner has pointed out above, the device of Thimsen et al disclose in figs. 2-5, including: a cutting instrument (11); an outer member (14) has an opening (16, 17) bounded by a cutting edge (58); a helical knife (18) coupled to the outer member for rotation relative to the outer member. The helical knife (18) has an edge (74, 76) to slide into tissue and the edge extends through the opening to form an outer periphery of the cutting instrument (see col. 6, lines 57-68). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the surgical cutting instrument of Thimsen would

have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, at least claims 1, 18 and 25 of the invention are not defined over the Thimsen '064 reference.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M.).

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn *✓*
May 17, 2004



JULIAN W. WOO
PRIMARY EXAMINER